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EXAMINER	
GELLNER, JEFFREY L	

ART UNIT	PAPER NUMBER
3643	

DATE MAILED: 04/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/641,114	SHORTRIDGE ET AL.
	Examiner	Art Unit
	Jeffrey L. Gellner	3643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35 and 43-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35 and 43-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Withdraw of Finality

Upon reconsideration of the art, the finality of the rejection of the last Office action is withdrawn. Besides the previous stated prior art rejections, a rejection based upon patenting follows.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24, of copending Application No. 09/251,953. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

For Claim 1 of the instant application and Claim 40 of 09/251,953, both claims disclose a method of preparing nongenetically modified seed by certifying the crop was grown and harvested under conditions to limit seed to 5% or less genetically modified seed, and making into a food product. It would have been obvious to one of ordinary skill in the art at the time of the

invention to modify the the method of 09/215,953 by certifying the crop was processed under conditions so that the processed food product contains 5% or less genetically modifed crop material since crops are made into food products and GMO free food products may command a greater price in the marketplace.

For Claim 1 of the instant application and Claim 40 of 09/251,953, both claims disclose a method of preparing nongenetically modified seed by certifying the crop was grown and harvested under conditions to limit seed to 5% or less genetically modified seed, and making into a food product. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the the method of 09/215,953 by certifying the crop was processed under conditions so that the processed food product contains 5% or less genetically modifed crop material since crops are made into food products and GMO free food products may command a greater price in the marketplace.

For Claim 43 of the instant application and Claim 40 of 09/251,953, both claims disclose a method of preparing nongenetically modified seed by certifying the crop was grown and harvested under conditions to limit seed to 5% or less genetically modified seed, and making into a food product. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the the method of 09/215,953 by certifying the crop was processed under conditions so that the processed food product contains 5% or less genetically modifed crop material since crops are made into food products and GMO free food products may command a greater price in the marketplace.

Dependent claims 2-35 and 4-61 are obvious in view of the dependent claims in 09/251,953.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 6-10, 13-21, 22-25, 28,29, 30-33, and 43-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poehlman (document AEE from Applicant's 1449) in view of Reuters (Chicago Sports Final Ed., page 4, 3 Sept. 1998).

As to Claim 1, Poehlman discloses the method steps of preparing a non-genetically modified processed food product (defined as, for example, at wheat grown as certified see that is used for bread production) comprising certifying the seed was planted and grown under conditions effective for harvesting a crop containing 5% or 1% or less genetically modified seed, (page 451, col. 2, sections b and d, and visually inspecting field for any crop plant growing and eliminating off-types whether they be genetically or nongenetically modified), and harvesting, processing (defined as cleaning seed with screens etc.) and certifying the crop (page 451, col. 2, section f). The purity of seed at the 5% or less level is shown by the certified seed tag (page 450, Fig. 20.2) with the row for "Other Crop Seed" and the accompanying percentage column. Not disclosed is certifying the seed contains 5% or less of genetically modified crop material.

Reuters, however, discloses the motivation to certify for contamination by genetically modified crop material. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman by certifying for contamination by genetically modified crop material so as to be able to sell their harvest (see Reuters).

As to Claims 2,3, 52-55, Poehlman as modified by Reuters does not disclose the certifying step producing a crop effective for producing a processed food containing 1, 0.1, or 0.01% or less genetically modified seed. However, Poehlman discloses seed with levels of "Other Crop Seed," "Weed Seed," and "Noxious Seed" as "None." It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman as modified by Reuters to include genetically modified seed in these three categories when they are the existing off-types to insure high yields with pure seed.

As to Claims 6 and 7, Poehlman does not disclose the certifying of using an application susceptibility test for producing a crop effective for producing a processed food containing 1, 0.1, or 0.01% or less genetically modified seed. However, Poehlman discloses seed with levels of "Other Crop Seed," "Weed Seed," and "Noxious Seed" as "None." Examiner takes official notice that susceptibility tests, such as ELISA and tests with antibodies, are old and notorious well known in the agronomic and plant genetics arts as a test to ID genotype or phenotype. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman as modified by Reuters by using susceptibility tests to include genetically modified seed in these three categories when they are the existing off-types to insure high yields with pure seed.

As to Claims 8-10, not disclosed is testing for genetically modified seed prior to planting, harvesting, and processing. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman as modified by Reuters by testing for genetically modified seed contamination prior to planting, harvesting and processing to ensure purity since consumer groups in Asia and the EU have generated a tide of protest against the use of genetically modified seed in foods (see Reuters).

As to Claims 13,14, 17, 20, and 21, Poehlman as modified by Reuters further disclose the nongenetically modified crop being small grains, rice, soybeans, or corn (see Poehlman pages 456 and 457).

As to Claims 15,16,18, and 19, the limitation of contamination being less than 0.1% is disclosed as described above. Not disclosed is the food product being corn sweetener or soy sauce. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman as modified by Reuters by making the crop into corn sweetener or soy sauce because these foods are well known uses for these crops.

As to Claims 22, Poehlman discloses the method steps of growing and harvesting a pure line of seed used for a processed food product (defined as, for example, at wheat grown as certified see that is used for bread production) comprising certifying the seed was planted and grown under conditions effective for harvesting a crop containing 5% or 1% or less off-types modified seed, (page 451, col. 2, sections b and d, and visually inspecting field for any crop plant growing and eliminating off-types whether they be genetically or nongenetically modified), and harvesting, processing (defined as cleaning seed with screens etc.) and certifying the crop (page

451, col. 2, section f). The purity of seed at the 5% or less level is shown by the certified seed tag (page 450, Fig. 20.2) with the row for "Other Crop Seed" and the accompanying percentage column. Not disclosed is certifying the seed contains 5% or less of non genetically modified crop material when the pureline is genetically modified seed. Reuters, however, discloses the motivation to certify for contamination by genetically modified crop material. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman by certifying for contamination by either genetically modified or nongenetically modified crop material so as to be able to sell their harvest (see Reuters).

As to Claims 23-25 and 56-58, Poehlman as modified by Reuters does not disclose the certifying step producing a crop effective for producing a processed food containing 1, 0.1, or 0.01% or less genetically modified seed. However, Poehlman discloses seed with levels of "Other Crop Seed," "Weed Seed," and "Noxious Seed" as "None." It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman as modified by Reuters to include nongenetically modified seed in these three categories when they are the existing off-types to insure high yields with pure seed.

As to Claims 28 and 29, Poehlman does not disclose the certifying of using an application susceptibility test for producing a crop effective for producing a processed food containing 1, 0.1, or 0.01% or less genetically modified seed. However, Poehlman discloses seed with levels of "Other Crop Seed," "Weed Seed," and "Noxious Seed" as "None." Examiner takes official notice that susceptibility tests, such as ELISA and tests with antibodies, are old and notorious well known in the agronomic and plant genetics arts as a test to ID genotype or phenotype. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify

the method of Poehlman as modified by Reuters by using susceptibility tests to include genetically modified seed in these three categories when they are the existing off-types to insure high yields with pure seed.

As to Claims 30-33, not disclosed is testing for genetically modified seed prior to planting, harvesting, storing, and processing. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman as modified by Reuters by testing for genetically modified seed contamination prior to planting, harvesting, including cleaning equipment before harvest and bins for storage, and processing to ensure purity since consumer groups in Asia and the EU have generated a tide of protest against the use of genetically modified seed in foods (see Reuters).

As to Claims 43, Poehlman discloses the method steps of growing and harvesting a pure line of seed used for a processed food product (defined as, for example, at wheat grown as certified see that is used for bread production) comprising certifying the seed was planted and grown under conditions effective for harvesting a crop containing 5% or 1% or less off-types modified seed, (page 451, col. 2, sections b and d, and visually inspecting field for any crop plant growing and eliminating off-types whether they be genetically or nongenetically modified), and harvesting, processing (defined as cleaning seed with screens etc.) and certifying the crop (page 451, col. 2, section f). The purity of seed at the 5% or less level is shown by the certified seed tag (page 450, Fig. 20.2) with the row for "Other Crop Seed" and the accompanying percentage column. Not disclosed is inspecting the processing facility before processing the crop to maintain a product containing 5% or less of genetically modified crop material. Reuters, however, discloses the motivation to maintain pure crop material from farmer's field to food

product. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman by inspecting and keeping clean the processing food plants as motivated by Reuters so that food producers can sell their product.

As to Claims 44-51 and 59-61, these limitations are disclosed in a similar manner as described above or below.

Claims 4,5, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poehlman (document AEE from Applicant's 1449) in view Reuters (Chicago Sports Final Ed., page 4, 3 Sept. 1998) in further view of *Use of DNA in Identification* (document AU on Applicant's 1449) (hereinafter "Lander").

As to Claims 4 and 5, the limitations of Claim 1 are disclosed as described above. A certifying step using genetic testing is not disclosed. Lander, however, discloses using genetic tests (DNA technology) to distinguish among genotypes (pages 1,2,and 6) and the 1 or 0.01% levels can be achieved by increasing the size of sample . It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the steps as disclosed in Poehlman as modified by Reuters by using genetic testing (DNA fingerprinting) as disclosed by Lander in the certifying step so as to increase the purity of seed planted or use as a processed seed product so as to increase yield by not having off-types.

As to Claims 26 and 27, the limitations of Claim 22 are disclosed as described above. A certifying step using genetic testing is not disclosed. Lander, however, discloses using genetic tests (DNA technology) to distinguish among genotypes (pages 1,2,and 6) and the 1 or 0.01% levels can be achieved by increasing the size of sample . It would have been obvious to one of

ordinary skill in the art at the time of the invention to modify the steps as disclosed in Poehlman as modified by Reuters by using genetic testing (DNA fingerprinting) as disclosed by Lander in the certifying step so as to increase the purity of seed planted or use as a processed seed product so as to increase yield by not having off-types.

Claims 11, 12, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poehlman (document AEE from Applicant's 1449) in view Reuters (Chicago Sports Final Ed., page 4, 3 Sept. 1998) in further in view of Montanari et al. (5,478,990; document AD on Applicant's 1449).

As to Claim 11, the limitations of Claim 1 are disclosed as described above. Not disclosed is the use of lot ID numbers which track the lot during processing. Montanari et al., however, discloses the use of ID tracking of food products from point of origin (see abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman as modified by Reuters by using a tracking ID from point of origin through the processing phase so as to track contaminants such as pathogens (see abstract of Montanari et al.)

As to Claim 12, Poehlman as modified by Reuters as further modified by Montanari et al. further disclose establishing an ID number when the crop is harvested (see abstract of Montanari et al.)

As to Claim 34, the limitations of Claim 1 are disclosed as described above. Not disclosed is the use of lot ID numbers which track the lot during processing. Montanari et al., however, discloses the use of ID tracking of food products from point of origin (see abstract). It

would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Poehlman as modified by Reuters by using a tracking ID from point of origin through the processing phase so as to track contaminants such as pathogens (see abstract of Montanari et al.)

As to Claim 35, Poehlman as modified by Reuters as further modified by Montanari et al. further disclose establishing an ID number when the crop is harvested (see abstract of Montanari et al.)

Response to Arguments

This response is to arguments raised in Applicant's Response entered 3 February 2003 as paper no. 17. The Applicant's arguments have been fully considered but they are not persuasive. Basically, Examiner continues to maintain his reasoning as stated in the previous office action's response to arguments.

Applicant's argument are that ❶ indefinteness is not found where a claim recites a percentage level without an accompanying probability level (*p*) (Response page 8 last para.); ❷ Poehlman's visual screening procedures are inadequate for distinguishing between GMO and nonGMO crops and processed grain (Response page 10 1st complete para.); ❸ Poehlman does not disclose or suggest farming activities such as keeping equipment and storage facilities clean, planting and harvesting pure seed, and actively maintaining pure seed by the phrase "offers useful service by encouraging the general use of pure seed on improved varieties throughout the state" (Response page 10 2nd complete para.); ❹ Neither Poehlman or Reuters can address the complexities involved in farming and processing GMO-free , non-GMO crops (Response page

10 last para.); ❺ Neither Lander nor Reuters provides motivation to combine with Poehlman (Response page 11 5th para.); and, ❻ Montanari is directed towards identifying animals and there exists no motivation to combine with Poehlman or Reuters (Response page 14 penultimate para.).

As to ❶ Examiner has with drawn the rejection.

As to ❷ Examiner considers Poehlman's visual screening procedures to be adequate to distinguish between genotypes when they cause different phenotypes regardless of the seed being GMO or nonGMO. Applicant states that many GMO and nonGMO varieties are visually phenotypically identical. Some varieties are not; Poehlman's techniques, known in the agronomic art since at least the mid-seventies, would adequately distinguish these genotypes at any level of purity desired.

As to ❸ Examiner considers Poehlman to disclose methods for keeping seed pure for both breeder and farmer seed. Examiner considers the 1st sentence (specifically, "offers useful service by encouraging the general use of pure seed of improved varieties throughout the state") of the section entitled "Agricultural Extension Services" on page 456 to have within its ambit the concepts of keeping equipment and storage facilities clean, planting and harvesting pure seed, and actively maintaining pure seed. Good farming methods dictates equipment clean and in good working condition, fields free of weeds and off-types, and planting pure, viable seed.

As to ❹ Examiner considers the combination of Poehlman and Reuters to be proper because Poehlman discloses the concept and methods of maintaining pure seed and Reuters discloses the concept of the need to guard against contamination by GMOs. These concepts are constant regardless of the complexity of the operation. Both references have a goal of

maintaining pure seed. Further, it would be obvious to one of ordinary skill in the art at the time of the invention to expand the methods of Poehlman to include maintenance against contamination by GMOs.

As to ❺ Examiner considers the combination of Poehlman/Reuters with Lander to be proper because Lander discloses a method of separating phenotypes by comparing genotypes with DNA fingerprinting. Lander's goal is, in essence, the same goal as that of Poehlman and Reuters achieved by a different means.

As to ❻ Examiner considers Montanari to disclose the concept of tracking particular food products from point of origin. Although Montanari's ID is used with animals the goal is compatible with the goal of Poehlman which is maintaining pure seed. Examiner considers it proper to combine the concept and methods of maintaining pure seed lots with the concept and method of tracking livestock because grain and livestock are both destined to be food products..

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeffrey L. Gellner whose phone number is 703.305.0053. The Examiner can normally be reached Monday through Thursday from 8:30 am to 4:00 pm. The Examiner can also be reached on alternate Fridays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Peter Poon, can be reached at 703.308.2574. The official fax telephone number for the Technology Center where this application or proceeding is assigned is 703.872.9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.1113.

Jeffrey L. Gellner